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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,112	10/28/2003	Frank B. Gelder	VIR-021011CO01	4731

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,112	GELDER, FRANK B.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *159-220* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *159-220* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction Requirement

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication received 03 January, 2005. Applicant is hereby advised that the last office action is being vacated in favor of the following office action. Claims 159-220 are pending in the instant application.

37 C.F.R. § 1.126

Applicant is advised that the numbering of claims is not in accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). **Misnumbered claim 210 (as set forth on the last page of the preliminary amendment received 28 October, 2004) has been renumbered claim 220.**

Claim Objections

Claim(s) 169, 177, and 179 are objected to because of the following informalities: claim 169 references a "muralyl dipeptide" which should read --muramyl dipeptide--. Claim 177 references the same polypeptide twice (e.g., see items (e) and (i), which both reference amino acids 69-94 of PR). Claim 179 simply references different antigens (e.g., p7, p10, p66) without specifying their genomic origins (i.e., p7 NC, p10 PR, p66/55 RT). Appropriate correction is required.

37 C.F.R. § 1.142

The following is a quotation of 37 C.F.R. § 1.142:

> (a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it **may be made at any time before final action.**
> (b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

35 U.S.C. § 121

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 4-27 of HIV gp120**, classified in class 424, subclass 188.1.

b. Group II, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 54-76 of HIV gp120**, classified in class 424, subclass 188.1.

c. Group III, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 502-541 of HIV gp41**, classified in class 424, subclass 188.1.

d. Group IV, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 254-295 of HIV RT (p66/55)**, classified in class 424, subclass 188.1.

e. Group V, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 69-94 of HIV PR (p10)**, classified in class 424, subclass 188.1.

f. Group VI, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 166-181 of HIV CA (p24)**, classified in class 424, subclass 188.1.

g. Group VII, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 390-410 of HIV NC (p7)**, classified in class 424, subclass 188.1.

h. Group VIII, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 438-443 of HIV NC (p7)**, classified in class 424, subclass 188.1.

i. Group IX, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 2-23 of HIV MA (p17)**, classified in class 424, subclass 188.1.

j. Group X, claim(s) 159-177, 180-182, 187, and 188, drawn to a vaccine composition comprising a viral polypeptide corresponding to **amino acids 89-122 of HIV MA (p17)**, classified in class 424, subclass 188.1.

k. Group XI, claim(s) 159-174, 178, 179, 180-182, 187, and 188, drawn to a vaccine composition comprising a **deglycosylated HIV gp120**, classified in class 424, subclass 208.1.

l. Group XII, claim(s) 159-174, 178, 179, 180-182, 187, and 188, drawn to a vaccine composition comprising a **deglycosylated HIV gp41**, classified in class 424, subclass 208.1.

m. Group XIII, claim(s) 159-174, 178, 179, 180-182, 187, and 188, drawn to a vaccine composition comprising a **deglycosylated HIV CA (p24)**, classified in class 424, subclass 208.1.

n. Group XIV, claim(s) 159-174, 178, 179, 180-182, 187, and 188, drawn to a vaccine composition comprising a **deglycosylated HIV NC (p7)**, classified in class 424, subclass 208.1.

o. Group XV, claim(s) 159-174, 178, 179, 180-182, 187, and 188, drawn to a vaccine composition comprising a **deglycosylated HIV PR (p10)**, classified in class 424, subclass 208.1.

p. Group XVI, claim(s) 159-174, 178, 179, 180-182, 187, and 188, drawn to a vaccine composition comprising a **deglycosylated HIV RT (p66/55)**, classified in class 424, subclass 208.1.

q. Group XVII, claim(s) 159 and 183, drawn to a vaccine composition comprising a combination of **multiple viral immunogens**, classified in class 424, subclass 202.1.

r. Group XVIII, claim(s) 159, 185, and 186, drawn to a vaccine composition comprising a an epitope that corresponds to **human α-fetal protein**, classified in class 424, subclass 184.1.

s. Group XIX, claim(s) 159, 185, and 186, drawn to a vaccine composition comprising a an epitope that corresponds to **aspartyl protease**, classified in class 424, subclass 184.1.

t. Group XX, claim(s) 159, 185, and 186, drawn to a vaccine composition comprising a an epitope that corresponds to **deoxyuridine-triphosphate nucleotidohydrolase**, classified in class 424, subclass 184.1.

u. Group XXI, claim(s) 159, 185, and 186, drawn to a vaccine composition comprising a an epitope that corresponds to **eosinophil cationic protein**, classified in class 424, subclass 184.1.

v. Group XXII, claim(s) 159, 185, and 186, drawn to a vaccine composition comprising a an epitope that corresponds to **eosinophil-derived neurotoxin**, classified in class 424, subclass 184.1.

w. Group XXIII, claim(s) 159, 185, and 186, drawn to a vaccine composition comprising a an epitope that corresponds to a **ribonuclease-4-precursor**, classified in class 424, subclass 184.1.

x. Group XXIV, claim(s) 189-196, drawn to a vaccine composition comprising a **nucleic acid** encoding a modified **Gag** polypeptide, classified in class 536, subclass 23.72.

y. Group XXV, claim(s) 189-196, drawn to a vaccine composition comprising a **nucleic acid** encoding a modified **Pol** polypeptide, classified in class 536, subclass 23.72.

z. Group XXVI, claim(s) 189-196, drawn to a vaccine composition comprising a **nucleic acid** encoding a modified **Env** polypeptide, classified in class 536, subclass 23.72.

aa. Group XXVII, claim(s) 197-208, drawn to a vaccination **method** employing a modified **Gag** polypeptide, classified in class 424, subclass 208.1.

bb. Group XXVIII, claim(s) 197-208, drawn to a vaccination **method** employing a modified **Pol** polypeptide, classified in class 424, subclass 208.1.

cc. Group XXIX, claim(s) 197-208, drawn to a vaccination **method** employing a modified **Env** polypeptide, classified in class 424, subclass 208.1.

dd. Group XXX, claim(s) 209-220, drawn to a vaccination **method** employing a **nucleic acid** encoding a modified **Gag** polypeptide, classified in class 536, subclass 23.72.

ee. Group XXXI, claim(s) 209-220, drawn to a vaccination **method** employing a **nucleic acid** encoding a modified **Pol** polypeptide, classified in class 536, subclass 23.72.

ff. Group XXXII, claim(s) 209-220, drawn to a vaccination **method** employing a **nucleic acid** encoding a modified **Env** polypeptide, classified in class 536, subclass 23.72.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-23 are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each group is directed toward a structurally and functionally different polypeptide (e.g., aa 4-27 of HIV gp120, aa 502-541 of HIV gp41, aa 390-410 of HIV NC, human α-fetal protein, etc.). The modified polypeptides do not share any common structural features and will all necessitate independent searches. Accordingly, each identified group is clearly directed toward a different inventive concept.

Inventions 24-26 are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the nucleic acids is directed toward a structurally and functionally different structural region (e.g., Gag, Pol, or Env). The modified nucleotides do not share any common structural features and will all necessitate independent searches. Accordingly, each identified group is clearly directed toward a different inventive concept.

Inventions 1-23 and 24-26 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each group is directed toward structurally and functionally different macromolecules (e.g., proteins or nucleic acids). Since the various groups do not share a common structural feature, separate searches will be required for each group. Clearly, each identified group is directed toward a different inventive entity.

Inventions 27-29 and 30-32 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each group is directed toward a methodology that employs structurally and functionally different reagents (e.g., polypeptide vaccines, nucleic acid vaccines). Clearly, each group is directed toward a different inventive concept.

Inventions 1-23 and 30-32 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of groups 30-32 neither require nor utilize the compounds of groups 1-23.

Inventions 24-26 and 27-29 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of groups 27-29 neither require nor utilize the nucleic acids of groups 24-26.

Inventions 1-23 and 27-29 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, each of the modified viral polypeptides can be employed in a materially different methodology such as affinity purification or enzymatic assays.

Inventions 24-26 and 30-32 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of groups 24-26 can be used in a materially different process such as hybridizaiton assays to detect virus.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

Claim Rejoinder (M.P.E.P. § 821.04)

Applicants are reminded that a restriction between product and process claims has been set forth *supra*. When applicant elects claims directed to the product, and a product claim is subsequently found to be allowable, withdrawn process claims that depend from or otherwise include **all** the limitations of the allowable product claim will be rejoined in accordance with the provisions of § 821.04 of the M.P.E.P. Process claims that depend from or otherwise include **all** the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116 while amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims **must** meet all criteria for patentability as set forth under 35 U.S.C. §s 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so will result in a loss of the right to rejoinder.** Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Correspondence

The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access

to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

24 July, 2005